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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/670,096	09/26/2000	Linda S. Mansfield	MSU 4.1-526	7494

21036 7590 01/23/2003

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EXAMINER
BASKAR, PADMAVATHI

ART UNIT	PAPER NUMBER
1645	4

DATE MAILED: 01/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Appli ation No.	Applicant(s)	
	09/670,096	MANSFIELD ET AL.	
	Examiner	Art Unit	
	Padmavathi v Baskar	1645	

-- Th MAILING DATE of this communication appears on the cover she t with the correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 October 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3, 21 and 22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,21 and 22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Response to Amendment

1. The amendment filed on 10/9/02 has been entered into the record. Claims 1, 2, 3 and 21 have been amended. Claims 1-3 and 21-22 are under examination.

2. The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.

Rejection Maintained

3. The rejection of claims 21 and 22 under 35 U.S.C. 112, first paragraph is maintained as set forth in the previous office action.

Claims 21-22 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are directed to a method of treating an equid infected with S.neurona comprising providing antibodies against 16 ± 4 kD and 30 ± 4 kD antigen of Sarcocystis neurona both of which are specific to S.neurona.

The nature of the disclosed invention is a method of treating an equid infected with S.neurona comprising providing antibodies against 16 ± 4 kD and 30 ± 4 kD antigen of Sarcocystis neurona both of which are specific to S.neurona.

The specification discloses that the antibodies of the instant claims are intended for use as therapeutic composition in a method for treating S.neurona infection in an equid. The specification, however, provides no working examples demonstrating (i.e., guidance) enablement for any *in vivo* method of treating an equid with the claimed antibodies against 16 ± 4 kD and 30 ± 4 kD antigen of Sarcocystis neurona. The treatment of S.neurona infection in an

equid with antibodies is highly complex and unpredictable because Liang et al 1998 (Infection and Immunity; 66 (5) 1834-1838) teach that antibodies to Sn 30 antigen has no protective activity in neutralizing the merozoites even in an in vitro assay. Further, Liang *et al.* teach that antibody to Sn 14 antigen is more effective in neutralization than antibody to Sn16 antigen (page 1836, left column, lines 1-6 and). Therefore, it is unpredictable whether the claimed antibodies could be useful in a method of treating an equid infected with S.neurona. In addition, the specific antibodies, which bind to 16kD and 30 kD antigens required to practice the claimed invention, are not disclosed in the instant specification. The high degree of unpredictability associated with the claimed method and lack of specific guidance in the specification would require an undue amount of experimentation without a predictable degree of success on the part of the skilled artisan.

Applicants' arguments filed on 10/9/02 have been fully considered but they are not deemed to be persuasive.

Applicant states that the cited Liang's art suggests that antibodies against 14kD and 16kD antigen would be efficacious in inhibiting disease caused by S.neurona and applicant's claimed vaccine consists antibodies against 16 kD and 30kD antigens and therefore, the claimed invention is consistent with the teachings of Liang.

It is the examiners position that certainly Liang et al disclose 14kD and 16kD antigens are important vaccine candidates and antibody to Sn 14 antigen is more effective in *in vitro* neutralization assay than antibody to Sn16 antigen. However, Liang et al show that the antibodies to 30kD antigen are non-neutralizing. Therefore, antibodies against 16 kD and 30kD antigens would treat an equid infected S. neurona is unpredictable since newly released parasites exposed to the antibodies for a short-time in vivo and the access of neutralization-sensitive epitopes on merozoites to antibody may be limited. Therefore, the efficacy of these

antibodies in an infected horse needs further experimentation. Further, applicant has not provided any evidence to show that the antibodies to16kD and 30kD antigens are ~~effective~~ to treat in an equid infected with S.neurona. Therefore, this rejection is maintained.

4. The rejection of claims 1-3 under 35 U.S.C. 102(b) as being anticipated Liang et al 1998 (Infection and Immunity; 66 (5) 1834-1838) is maintained as set forth in the previous office action.

The claims are directed to a composition comprising isolated antibodies, which are against a 16 ± 4 KD antigen and 30 ± 4 KD antigen of S.neurona both of which are specific to S.neurona.

Liang et al 1998 (see figure 1 and 2) disclose isolated equine antibodies (i.e., serum antibodies are polyclonal antibodies) which are against a 16 ±4 kD antigen and 30 ±4 kD antigen of S.neurona both of which are specific to S.neurona (see binding pattern of antibodies to Sn 30 kD and Sn16 kD antigens in figure 1 E). Serum and CSF samples from different infected horses were selected and obtained. These samples were filtered through 0.22- µm-pore size syringe filters (see page 1834, right column, 4th paragraph under clinical samples and page 1835, left column, under neutralization assay). Thus the composition comprises a mixture of antibodies. In the absence of evidence to the contrary the disclosed prior art antibodies and the claimed antibodies are the same. Since the Office does not have the facilities for examining and comparing applicants' product with the product of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430.

A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the

claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Applicants' arguments filed on 10/9/02 have been fully considered but they are not deemed to be persuasive.

Applicant states that the amended claim recites that the composition comprises a mixture of isolated antibodies and the cited prior art composition does not contain isolated antibodies. The examiner disagrees with the applicant because Liang's art discloses that serum samples were collected and filtered through 0.22- μm-pore size filter indicating that the composition comprising antibodies have been isolated from infected horse serum which is obtained from blood (serum is isolated from blood). Further applicant asserts that the composition cited in the prior art contains other cross-reacting antibodies and infectious S.neurona without providing any side-by-side comparison of the claimed composition with the composition of art of record. It is the examiner's position that applicant is arguing limitations which are not set forth in the claims. Lastly applicant argues that serum or CSF from horses does not always contain antibodies to 16kD and 30kD antigens and most importantly the claimed invention does not contain infectious S.neurona. Again, the cited prior art composition has been shown to contain antibodies to 16kD and 30kD antigen (see binding pattern of antibodies to Sn 30 kD and Sn16 kD antigens in figure 1 E). Therefore, in the absence of evidence to the contrary the prior art composition, which is filtered through 0.22- μm-pore size filter, does not contain infectious S.neurona. Therefore, the rejection of record is maintained.

5. No claims are allowed.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padma Baskar whose telephone number is (703) 308-8886. The examiner can normally be reached on Monday through Friday from 6:30 AM to 4 PM EST

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Padma Baskar Ph.D.

12/15/02

LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600